IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

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COMPLAINT

Plaintiff Celsis In Vitro, Inc. ("Celsis" or "Plaintiff") for its Complaint for patent infringement against Defendants XenoTech, LLC ("XenoTech"), Sekisui Medical Co., Ltd. ("Sekisui Medical"), and Sekisui Chemical Co., Ltd. ("Sekisui Chemical") (collectively, "Defendants"), alleges as follows:

Nature of the Action

1. Plaintiff Celsis brings this action for infringement of United States Patent No. 7,604,929 ("the '929 patent") arising under the Patent Law of the United States, 35 U.S.C. § 100 *et seq*. This action relates to processes and methods used to manufacture, use, sell, offer for sale, and/or export products and the *in vitro* services performed by

Defendant XenoTech, at the direction and control of Defendants Sekisui Medical and Sekisui Chemical, that infringe one or more claims of the '929 patent.

Plaintiff Celsis

- 2. Plaintiff Celsis In Vitro, Inc. (formerly known as In Vitro Technologies, Inc.) is a Maryland corporation having a principal place of business located at 1450 South Rolling Road, Baltimore, Maryland 21227, and a corporate office located within this judicial district at 600 West Chicago Avenue, Suite 625, Chicago, Illinois 60654.
- 3. Plaintiff Celsis is a division of Celsis International Ltd., an international leading provider of innovative life science products and laboratory services to the pharmaceutical and consumer products industries.
- 4. Plaintiff Celsis is a leading global supplier of high-quality cryopreserved and fresh liver cells (hepatocytes) for *in vitro* research in preclinical drug discovery and development. Such hepatocytes are used in research to determine Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) characterizations of potential drugs.
- 5. Plaintiff Celsis has proprietary expertise in hepatocyte and cryopreservation technologies which enable it to supply innovative testing products to customers in the pharmaceutical and biotechnology industries. By screening candidate compounds for their ADMET properties early in the drug discovery and development phases using Celsis' products, companies may reduce the time and development cost associated with developing new drugs.
 - 6. On October 20, 2009, the '929 patent, entitled "Cellular Compositions

and Methods for Their Preparation," was duly and legally issued by the United States

Patent and Trademark Office.

- 7. Plaintiff Celsis is the assignee of all right, title, and interest in and to the '929 patent, including all rights to sue and recover all damages for infringement.
- 8. Plaintiff Celsis has undertaken substantial efforts to protect its proprietary rights in its cryopreserved hepatocyte technologies by developing a comprehensive intellectual property portfolio in the United States and in foreign countries, including obtaining the '929 patent.
- 9. Plaintiff Celsis manufactures, sells, and markets products in this judicial district under the trade name LiverPoolTM, which it produces using the processes and methods of the '929 patent and has marked under 35 U.S.C. § 287(a) at all relevant time periods.

The Defendants XenoTech, Sekisui Chemical, and Sekisui Medical

- 10. Upon information and belief, Defendant XenoTech is a Kansas company with a principal place of business in Kansas, including a place of business at 16825 West 116th Street, Lenexa, Kansas 66219.
- 11. Upon information and belief, Defendant XenoTech employs account managers who service XenoTech's customers and potential customers within Illinois and this judicial district.

- 12. Upon information and belief, Defendant Sekisui Chemical is a Japanese company with its principal place of business at 2-4-4 Nishitenma, Kita-ku, Osaka 530-8565 Japan and another at 2-3-17 Toranomon, Minato-ku, Tokyo 105-8450 Japan.
- 13. Upon information and belief, on or about July 9, 2008, Defendant Sekisui Chemical purchased Defendant XenoTech and now XenoTech is a wholly-owned subsidiary of Sekisui Chemical.
- 14. Upon information and belief, Defendant Sekisui Medical is a Japanese company with a principal place of business located at KDX Nihombashi 313 Building 5F, 3-13-5, Nihombashi, Chuo-ku, Tokyo, 103-0027 Japan. Defendant Sekisui Medical is the wholly-owned subsidiary of Sekisui Chemical and is the exclusive distributor and seller in Japan of XenoTech's products made within the United States.
- 15. Upon information and belief, Defendant XenoTech is under the direct control of Sekisui Chemical, whose control is exercised with the active assistance of Defendant Sekisui Medical.
- 16. Upon information and belief, prior to Defendant Sekisui Chemical acquiring Defendant XenoTech, XenoTech did not manufacture, sell, or offer to sell any cryopreserved hepatocyte products or perform any testing services using pooled cryopreserved hepatocytes.

The Process for Producing the CryoXTremeTM and CryostaXTM Products and the Performance of Services Using Pooled Cryopreserved Hepatocytes

- During the summer of 2009, Plaintiff Celsis became aware that Defendant XenoTech was actively engaged in making, using, selling, offering for sale, and/or exporting hepatocyte products, such as $CryoXTreme^{TM}$, as well as providing *in vitro* drug testing services using pooled cryopreserved hepatocytes.
- 18. On October 20, 2009, Defendant XenoTech was attending and exhibiting at the 2009 International Society of the Study of Xenobiotics ("ISSX") Conference in Baltimore, Maryland.
- 19. On information and belief, XenoTech learned that the '929 patent had issued to Celsis during the ISSX Conference.
- 20. On or about November 4, 2009, Plaintiff Celsis provided written notice to Defendant XenoTech under 35 U.S.C. § 287(b)(5) identifying the CryoXTreme[™] products as potentially requiring a license under the '929 patent ("the Celsis Notice Letter").
- 21. On or about November 13, 2009, Defendant XenoTech responded to Plaintiff Celsis by stating that it had "initiated a review process of the patents [sic] claims that will allow [XenoTech] to address [Celsis'] offer."
- 22. After receiving the Celsis Notice Letter, but prior to providing a substantive response to Celsis, Defendant XenoTech introduced another pooled cryopreserved hepatocyte product called CryostaXTM through a press release.

- 23. On or about December 15, 2009, Defendant XenoTech provided a written response to the Celsis Notice Letter, stating only that: "Following receiving your November 4, 2009 offer to license U.S. Patent No 7,604,929 we reviewed the claims of the patent and our relevant procedures," and that "[b]ased on the outcome of the review, we are not interested in licensing the '929 patent."
- 24. During the nearly six weeks between receiving the Celsis Notice Letter and providing its written response to Plaintiff Celsis on December 15, 2009, XenoTech reviewed the claims of the '929 patent and its file history.
- 25. During the nearly six weeks between receiving the Celsis Notice Letter and providing its written response to Plaintiff Celsis on December 15, 2009, XenoTech reviewed its methods for making its products, including CryoXTremeTM and CryostaXTM, and its methods to perform *in vitro* drug testing services.
- 26. Upon information and belief, during the nearly six weeks between receiving the Celsis Notice Letter and providing its written response to Plaintiff Celsis on December 15, 2009, XenoTech consulted Defendants Sekisui Chemical and Sekisui Medical.
- 27. Defendant XenoTech's letter dated December 15, 2009, coupled with its press release regarding CryostaXTM on or about the same day, demonstrates its bad faith in failing to comply with 35 U.S.C. § 287(b)(5)(C) by providing no basis to Plaintiff Celsis for why the processes used to make at least its CryoXTremeTM products should not be licensed under the '929 patent.
 - 28. Upon information and belief, Defendant XenoTech actively sells, offers

to sell, and markets its CryoXTremeTM and CryostaXTM products and performs drug testing services for customers in Illinois, including this judicial district.

- 29. Upon information and belief, in order to earn convoyed revenues from the sales of CryoXTremeTM, Defendant XenoTech introduced its CryostaXTM products to migrate its customers away from its products produced using its infringing processes and methods (*i.e.*, CryoXTremeTM) to CryostaXTM.
- 30. Defendant XenoTech continues to use infringing processes and methods to manufacture and sell its products, including CryoXTremeTM, and continues to perform processes for its drug testing services, all of which have infringed and continue to willfully infringe at least one claim of the '929 patent.
- 31. Plaintiff Celsis has been harmed and continues to be harmed by Defendant XenoTech's infringing activities.
- 32. Upon information and belief, Defendant Sekisui Chemical, by itself or through its wholly-owned subsidiary and agent Defendant Sekisui Medical, directed Defendant XenoTech to continue providing pooled cryopreserved hepatocyte products and related testing services in the United States, including in Illinois and this judicial district, even after XenoTech received the Celsis Notice Letter.
- 33. As such, Defendant Sekisui Chemical, by itself or through its wholly-owned subsidiary and agent Defendant Sekisui Medical, caused tortious injury to Celsis by directing and controlling XenoTech's infringing activities in Illinois and this judicial district.

Jurisdiction and Venue

- 34. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.
- 35. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*: (1) their presence in Illinois and this judicial district; (2) their systematic and continuous contacts with Illinois and this judicial district; and (3) their tortious acts directed at Illinois and this judicial district under 735 ILCS 5/2-209(a)(2).
- 36. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

COUNT I

Patent Infringement under 35 U.S.C. § 271(a)

- 37. Plaintiff Celsis incorporates by reference paragraphs 1-36 of this Complaint.
- 38. On information and belief, Defendant XenoTech uses the processes and methods within the scope of one or more claims of the '929 patent by selling, offering to sell, and performing *in vitro* drug testing services using pooled cryopreserved hepatocytes.
- 39. On information and belief, Defendant XenoTech has intentionally and willfully infringed the '929 patent.

- 40. Plaintiff Celsis has been substantially and irreparably harmed by Defendant XenoTech's infringing activities and has been damaged as a result of such infringing activities.
 - 41. Plaintiff Celsis does not have an adequate remedy at law.
- 42. Plaintiff Celsis is entitled to damages as a result of Defendant XenoTech's infringing activities.

COUNT II

Patent Infringement under 35 U.S.C. § 271(g)

- 43. Plaintiff Celsis incorporates by reference paragraphs 1-42 of this Complaint.
- 44. On information and belief, Defendant XenoTech makes, uses, sells, offers to sell, and/or exports products which are made by a process or processes within the scope of one or more claims of the '929 patent.
- 45. On information and belief, Defendant XenoTech has intentionally and willfully infringed the '929 patent.
- 46. Plaintiff Celsis has been substantially and irreparably harmed by Defendant XenoTech's infringing activities and has been damaged as a result of such infringing activities.
 - 47. Plaintiff Celsis does not have an adequate remedy at law.

48. Plaintiff Celsis is entitled to damages as a result of Defendant XenoTech's infringing activities.

COUNT III

Patent Infringement under 35 U.S.C. § 271(c)

- 49. Plaintiff Celsis incorporates by reference paragraphs 1-48 of this Complaint.
- 50. On information and belief, Defendant XenoTech makes, uses, sells, offers to sell, and exports products from within the United States which are made by performing one of more steps with a process or processes within the scope of one or more claims of the '929 patent.
- 51. On information and belief, Defendant XenoTech has intentionally and willfully infringed the '929 patent.
- 52. Plaintiff Celsis has been substantially and irreparably harmed by Defendant XenoTech's infringing activities and has been damaged as a result of such infringing activities.
 - 53. Plaintiff Celsis does not have an adequate remedy at law.
- 54. Plaintiff Celsis is entitled to damages as a result of Defendant XenoTech's infringing activities.

COUNT IV

Patent Infringement under 35 U.S.C. § 271(b)

- 55. Plaintiff Celsis incorporates by reference paragraphs 1-54 of this Complaint.
- 56. On information and belief, Defendant Sekisui Chemical, by itself or through its agent Sekisui Medical, actively induced and continues to induce Defendant XenoTech to make, use, sell, offer to sell, and/or export products from within the United States which are made by a process or processes within the scope of one or more claims of the '929 patent.
- 57. On information and belief, Defendant Sekisui Chemical, by itself or through its agent Sekisui Medical, has intentionally and willfully infringed the '929 patent.
- 58. Plaintiff Celsis has been substantially and irreparably harmed by Defendant Sekisui Chemical's infringing activities and has been damaged as a result of such infringing activities.
 - 59. Plaintiff Celsis does not have an adequate remedy at law.
- 60. Plaintiff Celsis is entitled to damages as a result of Defendant Sekisui Chemical's infringing activities.

COUNT V

Patent Infringement under 35 U.S.C. § 271(b)

- 61. Plaintiff Celsis incorporates by reference paragraphs 1-60 of this Complaint.
- 62. On information and belief, Defendant Sekisui Medical, by itself or at the direction of Sekisui Chemical, actively induced and continues to induce Defendant XenoTech to make, use, sell, offer to sell, and/or export products from within the United States which are made by a process or processes within the scope of one or more claims of the '929 patent.
- 63. On information and belief, Defendant Sekisui Medical, by itself or at the direction of Sekisui Chemical, has intentionally and willfully infringed the '929 patent.
- 64. Plaintiff Celsis has been substantially and irreparably harmed by Defendant Sekisui Medical's infringing activities and has been damaged as a result of such infringing activities.
 - 65. Plaintiff Celsis does not have an adequate remedy at law.
- 66. Plaintiff Celsis is entitled to damages as a result of Defendant Sekisui Medical's infringing activities.

RELIEF SOUGHT

- A) A judgment and decree that the '929 patent is valid and enforceable;
- B) A judgment that Defendant XenoTech infringed the '929 patent under 35 U.S.C. §§ 271(a), 271(c), and/or 271(g).
- C) A judgment that Defendant Sekisui Chemical infringed the '929 patent under 35 U.S.C. § 271(b);
- D) A judgment that Defendant Sekisui Medical infringed the '929 patent under 35 U.S.C. § 271(b);
- E) A permanent injunction restraining and enjoining Defendants XenoTech, Sekisui Chemical, and/or Sekisui Medical and their respective officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacturing, sale, offer for sale or use within the United States, or exportation from the United States a product manufactured using the processes and methods of the '929 patent or perform drug testing services using the processes and methods of the '929 patent prior to March 6, 2026, the day after the current expiration of the '929 patent;
- F) An award of monetary relief for Defendant XenoTech's, Sekisui Chemical's, and/or Sekisui Medical's infringement of the '929 patent within the United States prior to the expiration of that patent, including any later expiration of any patent term extension or exclusivity for the patent to which Plaintiff Celsis becomes entitled, and that any such monetary relief be awarded to Celsis with prejudgment interest;

- G) A declaration that this case is exceptional and that Plaintiff Celsis is entitled to an award of attorneys' fees from Defendants XenoTech, Sekisui Chemical, and/or Sekisui Medical under 35 U.S.C. § 285; and
 - H) Such other and further relief as the Court may deem just and proper.

Dated: February 1, 2010

By: /s Jordan A. Sigale

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